REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

The claims at issue in this application define an injection needle having a needle point, and a liquid introducing instrument that includes such an injection needle. Claims 1 and 4 were amended in the previously filed Amendment to recite the outer diameter range of the puncture section of the injection needle, the outer diameter range of the proximal end section of the injection needle, and the length range from the puncture section to the tapered section. In addition, Claims 1 and 4 were amended to set forth that the tapered section possesses an outer profile forming an angle ranging in the manner claimed.

Now Claim 1 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Maruyama, Melker and newly cited reference Trudell, while Claim 4 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Gross, Melker and Trudell. As best understood, the Official Action rejects Claims 1 and 4 based on the view that it would have been obvious for one of ordinary skill to construct an injection needle/liquid introducing instrument having the features recited in the independent claims in view of the disclosures in Maruyama and Gross, the taper associated with the plastic dilator disclosed in Melker, and the disclosed outer diameters associated with portions of the lacrimal irrigating cannula disclosed in Trudell.

Applicants respectfully submit that one of ordinary skill would not have been motivated to combine the teachings in Maruyama/Gross, Trudell and Melker. Claims 1 and 4 define that the injection needle comprises, in combination with the other claimed features, a puncture section having a needle point to pierce a living body, a

proximal end section, and a tapered section interconnecting the puncture section and the proximal end section, wherein the outside diameter of the proximal end section ranges from 0.35 mm to 1 mm and the outside diameter of the puncture section ranges from 0.1 mm to 0.5 mm. As explained in the previously filed Amendment, the claimed construction of the injection needle advantageously reduces the degree of puncture pain experienced by the patient without unacceptably compromising the mechanical strength of the needle and increasing the flow passage resistance when a liquid medication is injected through the needle.

Trudell does not disclose, and is not concerned with, an injection needle that includes a puncture section having a needle point that pierces a living body. Rather, Trudell discloses a quite different type of instrument -- a lacrimal cannula that is specifically adapted to be inserted into the lacrimal puncta of the eye for purposes of irrigating and forcing out obstructions in the lacrimal ducts of the eye.

The Official Action seems to rely upon Trudell's disclosure of certain outer diameters without regard to the context in which such diameters are disclosed and without considering Trudell's disclosure in its entirety. This is improper. When one considers the disclosure in Trudell as a whole, it is apparent that the disclosed diameters are specifically selected to achieve certain objectives uniquely associated with the manner in which the lacrimal cannula is used. When considered in this context, no basis exists to support the position that Trudell's disclosure would have motivated one to use the same diameters in the needles shown in Maruyama and Gross.

First, the lacrimal cannula disclosed in Trudell is not an injection needle possessing a puncture section having a needle point for piercing a living body.

Rather, Trudell's lacrimal cannula is inserted into the lacrimal puncta of the eye. It is for this reason that the lacrimal cannula possesses a smoothly rounded distal end 8. Thus, an ordinarily skilled artisan would not view Trudell's disclosure of certain outer diameters as a teaching that should be applied to the needles shown in Maruyama and Gross.

As previously mentioned, the claimed outer diameters of the different sections of the injection needle at issue here help contribute to reducing the degree of puncture pain experienced by the patient. Trudell is not concerned with reducing the patient's puncture pain. Quite the contrary, as discussed below in more detail, Trudell is concerned with configuring a lacrimal cannula so that the same lacrimal cannula can be used for insertion, dilation, probing and irrigation of the lacrimal drainage system, thus avoiding the prior use of multiple cannulas.

The background portion of Trudell points out that prior known lacrimal cannulas suffer from the disadvantage that they are configured as a single diameter and are thus not well suited to performing the different tasks required of lacrimal cannulas, namely insertion into the puncta of the eye, dilation of the puncta, probing of the lacrimal duct and irrigation. Trudell notes that a large diameter lacrimal cannula is problematic because it requires extensive dilation of the puncta with a separate puncta dilating instrument. On the other hand, Trudell notes that a small diameter lacrimal cannula is problematic in that it is unable to prevent fluid backflush during the irrigation procedure. In addition, Trudell points out that a single diameter lacrimal cannula is not capable of providing a reliable indication of the depth of insertion of the instrument into the lacrimal canalicula.

To address these perceived shortcomings, Trudell proposes a lacrimal cannula possessing a smaller diameter shaft portion 12, a larger diameter shaft portion 15, and a taper connecting the different diameter shaft portions 12, 15. As discussed beginning in line 41 of column 3 of Trudell, the smaller diameter shaft portion 12 allows the lacrimal cannula to be inserted into the lacrimal puncta 28 without the need for a separate instrument to dilate the lacrimal puncta. As the lacrimal cannula is advanced and inserted deeper into the lacrimal canalicula 30 as shown in Fig. 4, the depth of insertion reaches the taper 14 and so the exact depth of insertion is known. Further insertion of the lacrimal cannula causes the larger diameter shaft portion 15 to be tightly gripped by the sphincter action of the lacrimal puncta 28 to thus prevent fluid backflush during the subsequent irrigation procedure.

It is thus seen that Trudell is specifically concerned with providing the lacrimal cannula with sections of different diameter for reasons specifically related to the manner in which the lacrimal cannula is used. The gauge of the smaller diameter section 12 is specifically selected so that when the lacrimal cannula is initially inserted into the lacrimal puncta 28, dilation of the lacrimal puncta is not required. Further, the gauge of the larger diameter section 15 is specifically selected so that the larger diameter section 15 is tightly gripped by the lacrimal puncta 28 to thus prevent fluid backflush when the irrigation procedure is performed.

Thus, an ordinarily skilled artisan would view Trudell's disclosure of a 26 or 27 gauge distal section and a 23 gauge proximal section as being specifically related to the manner in which the disclosed lacrimal cannula is used. Trudell describes that the 26 or 27 gauge distal section allows the lacrimal cannula to be inserted into the lacrimal puncta 28 without punctal dilation, and describes that the 23 gauge proximal

section allows the lacrimal puncta 28 to tightly grip the proximal section to prevent fluid backflush during irrigation. To the extent it can be said that Trudell's disclosure of different gauges represents a "teaching," it is merely that a lacrimal cannula can be constructed to possesses sections having different gauges as disclosed in order to achieve the objectives sought to be achieved by Trudell. However, to say that Trudell somehow teaches using the disclosed gauges in a variety of other quite different instruments is simply not supported by Trudell's disclosure.

Considering Trudell's disclosure in its entirety, as required by case law, an ordinarily skilled artisan would not have been motivated to use Trudell's disclosure of a 26 or 27 gauge distal section in devices other than a lacrimal cannula, and would not have been motivated to apply Trudell's disclosure of a 23 gauge proximal section in devices other than a lacrimal cannula. Those diameters were selected by Trudell because the disclosed instrument is used in an environment (i.e., lacrimal puntca and lacrimal canalicula/ducts) where those sizes are necessary to achieve the objectives with which Trudell is concerned. Quite clearly though, Trudell does not describe that the disclosed diameters/gauges also have useful application to devices other than lacrimal cannulas, for example injection needles that include a puncture section possessing a living body piercing needle point as claimed or the needles described in Maruyama and Gross. The Official Action does not explain why Trudell's disclosure of certain diameters/gauges would have motivated an ordinarily skilled artisan to incorporate the same diameters/gauges in injection needles which are not used in the same manner as a lacrimal puncta.

The comments near the bottom of page two of the Official Action state that Trudell discloses a “puncturing device” having a "puncturing section" which

possesses a diameter "that allows for the needle to make as small a puncture as possible". This is not correct. As pointed out above, Trudell is specifically concerned with the construction of a lacrimal cannula that is inserted into the lacrimal puncta 28 of the eye. The disclosed lacrimal cannula does not include a puncture section and is not used in any way to puncture or pierce a living body. This is apparent from the illustrations in Figs. 3 and 4 showing the lacrimal cannula during insertion into the lacrimal puncta 28. This is also apparent from Trudell's disclosure that the lacrimal cannula possesses a smoothly rounded distal end 8. This rounded distal end 8 is consistent with the fact that the lacrimal cannula is inserted into the lacrimal puncta 28 rather than being used to puncture a living body.

In addition, contrary to the observation in the Official Action, nowhere does Trudell state that the gauge of the smaller diameter section 12 is chosen so that the lacrimal cannula makes as small a puncture as possible. Rather, Trudell indicates that the gauge of the smaller diameter section 12 is chosen so as not to require dilation of the lacrimal puncta (see, for example, the discussion in lines 65-67 of column 1).

Because the stated rationale for combining Trudell with the needles disclosed in Maruyama and Gross is based on the erroneous belief that Trudell discloses a needle constructed to puncture a living body and make as small a puncture as possible, it is respectfully submitted that the Official Action has not established a *prima facie* case of obviousness under 35 U.S.C. § 103(a). In addition, for the reasons discussed above, a person skilled in the art would have recognized that Trudell's disclosure of certain diameters/gauges derives from the fact that the disclosed device is a lacrimal cannula that is specifically constructed and sized

based on its use as a lacrimal cannula. Thus, an ordinarily skilled artisan would not have been motivated to apply Trudell's disclosure of different diameters/gauges to devices other than a lacrimal cannula, such as an injection needle as claimed or the needles disclosed in Maruyama and Gross.

Turning now to Melker, the Official Action once again comments that Melker "teaches a **needle 1** with a taper from the distal end 5 to the transition point 6 having an angle in the range from about 1.26 degrees to 5.18 degrees" (emphasis added). However, as was pointed out in the prior response, Melker's reference to a taper applies to the dilator 4 which fits over the needle 1. That is, in Melker, it is not the needle 1 that possesses the disclosed taper, but rather the dilator 4 that fits over the needle. If the disclosure in Melker can be said to have any relevance to the needles described in Maruyama and Gross, it is merely that the disclosed needles can be used with a dilator having the noted taper. However, Claims 1 and 4 at issue here do not recite that the needle is used with a dilator having the claimed taper. Rather, Claims 1 and 4 recite that the injection needle itself possess a tapered section interconnecting the puncture section and the proximal end section, wherein the tapered section possesses an outer profile forming an angle in the range as claimed. Nowhere does Melker state or suggest that the taper on the dilator 4 should also be used on the needle 1. Other than the general comment on page 5 of the Official Action stating that "Melker discloses motivation to combine the taper of that invention with applicant's needle as discussed above," there is little explanation of why an ordinarily skilled artisan would have been led to understand that Melker's disclosure of a taper on a dilator should be applied to a needle. For the reasons summarized above and discussed in the earlier Amendment, it is respectfully submitted that the

disclosure in Melker would not have led one to modify the needles disclosed in Maruyama and Gross to include a tapered section having the taper recited in Claims 1 and 4.

The rejection under 35 U.S.C. § 103(a) is also improper because the disclosure in Trudell is contrary to the reasons stated in the Official Action for modifying the needles in Maruyama and Gross based on the Melker disclosure. As noted, Claims 1 and 4 recite the outer diameter range of the proximal end section (i.e., 0.35 mm to 1 mm) and the angle range of the taper of the tapered section (i.e., 0.5 degrees to 1 degree 20 minutes). The Official Action relies on Trudell's disclosure of a lacrimal cannula possessing a 23 gauge larger diameter section 15 and Melker's disclosure of a tapered dilator. As noted earlier, Trudell discloses that the taper 14 provides an insertion depth indicator while the larger diameter section 15 is specifically sized to tightly grip the lacrimal puncta. These objectives of providing a tight grip and providing an insertion depth indicator (the latter of which is presumably achieved by virtue of the taper 14 resisting easy insertion) are contrary to the rationale set forth in the Official Action for the proposed modification according to Melker's disclosure -- providing gentle entry into a vessel. Thus, Trudell would have actually led one away from combining its disclosure with the disclosure in Melker in the manner suggested in the Official Action.

For at least the same reasons discussed above, it is respectfully submitted that Claims 1 and 4 are allowable over a combination of the references cited in the Official Action. Accordingly, withdrawal of the rejections of record and allowance of this application are earnestly solicited.

Claims 3 and 5 recite additional features further distinguishing over the art of record. As these claims are allowable at least by virtue of their dependence from allowable independent claims, it is not necessary at this time to discuss these additional distinctions.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: August 18, 2006

By: _____
Matthew L. Schneider
Registration No. 32814

P.O. Box 1404
Alexandria, VA 22313-1404
703 836 6620